

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Alex C. Toy; John W. Forsberg	Confirmation No.	9367
Serial No.:	10/693,012		
Filed:	October 24, 2003	Customer No.:	28863
Examiner:	Darin Roberts		
Group Art Unit:	3762		
Docket No.:	1023-288US01		
Title:	MEDICAL DEVICE PROGRAMMER WITH REDUCED-NOISE POWER SUPPLY		

DECLARATION UNDER 37 C.F.R. 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

We, Alex C. Toy and John W. Forsberg, declare as follows:

1. We are named inventors in above-referenced Patent Application Serial No. 10/693,012.
2. We are employees of Medtronic, Inc., the Assignee of record for the present application.
3. The above-referenced Patent Application Serial No. 10/693,012 claims priority to Provisional Patent Application Serial No. 60/508,511 filed October 2, 2003.
4. More than one year prior to October 2, 2003, Medtronic, Inc. requested that Benchmark Electronics, Inc. manufacture 222 programmers for a medical device pursuant to assembly drawings shown in Exhibit A. Exhibit A is a two-page document assigned document number 502814 and relates to a programmer with model number 37741 ("Model 37741

programmer"). On sheet 1, Exhibit A illustrates an assembly view of a Model 37741 programmer for a medical device. On sheet 2, Exhibit A illustrates an assembled view of a Model 37741 programmer for a medical device. Medtronic Inc. confidential and proprietary information has been redacted from Exhibit A.

5. More than one year prior to October 2, 2003, Benchmark Electronics, Inc. manufactured 222 Model 37741 programmers pursuant to the request from Medtronic, Inc.

6. At least 89 of the 222 Model 37741 programmers manufactured by Benchmark Electronics, Inc. more than one year prior to October 2, 2003 were used for experimental purposes, as evidenced by Exhibits B-D. Exhibit B is a forty-nine page document assigned document number 288117-70205 and entitled, "Neuro Patient Programmer Platform Electrical DVT Report." Exhibit C is a one page screen print of an internal electronic document storage and retrieval system at Medtronic, Inc., which indicates that document number 288117-70205 (Exhibit B) was modified on October 7, 2002 and June 28, 2003. Exhibit D is a twenty-nine page document entitled, "DVT Test Data for 288117-70020," and summarizes the results of tests conducted in May 2002 and June 2002. Medtronic Inc. confidential and proprietary information has been redacted from Exhibits B and D.

7. The remainder of the 222 Model 37741 programmers manufactured by Benchmark Electronics, Inc. more than one year prior to October 2, 2003 were not used for the tests reflected in Exhibits B and D and were used internally by Medtronic, Inc. employees for development purposes.

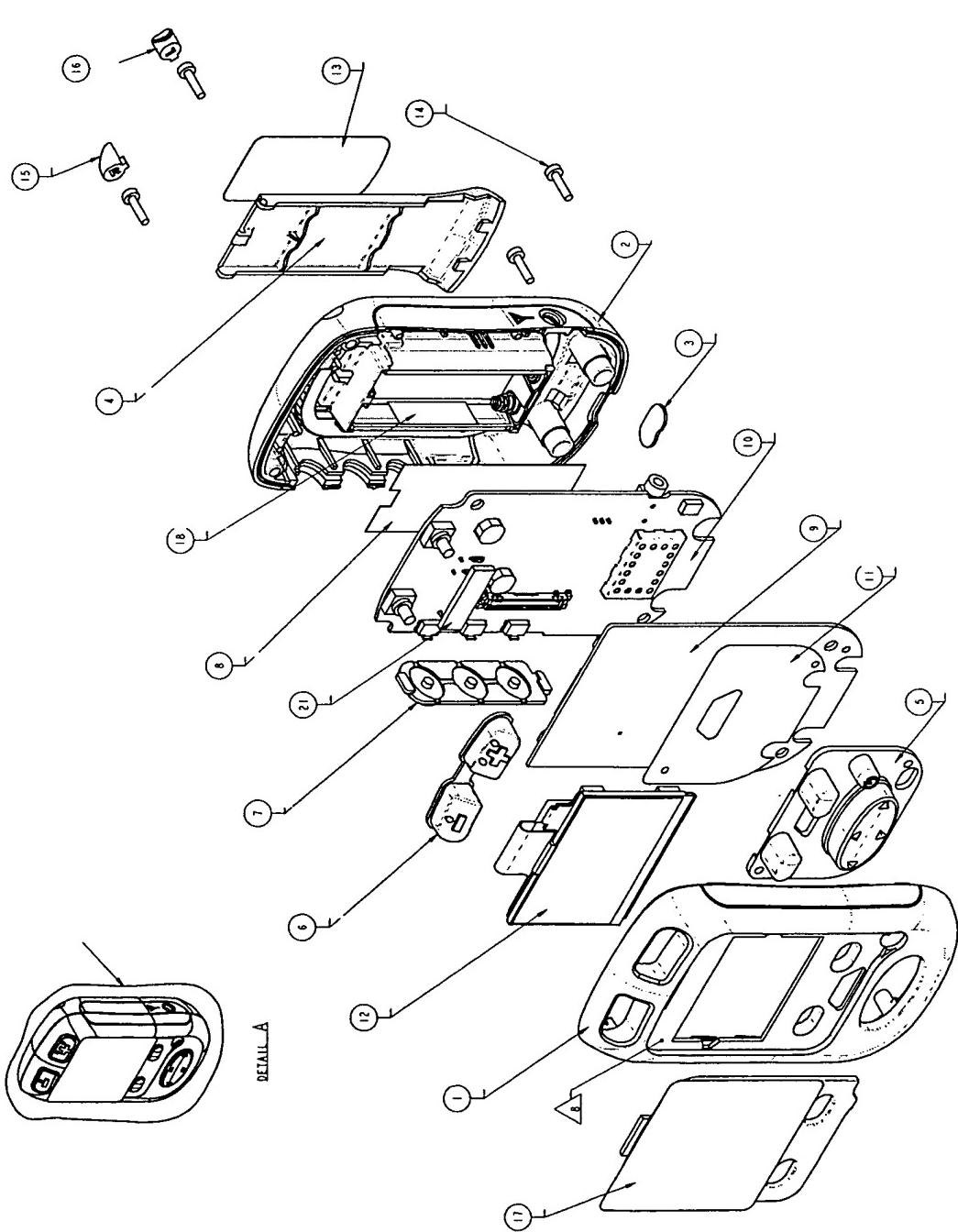
8. In view of this Declaration and the content of Exhibits A-D, it is clear that the 222 Model 37741 programmers manufactured by Benchmark Electronics, Inc. were not "in public use or on sale in this country, more than one year prior to the date of application for patent in the United States" under 35 U.S.C. § 102(b).

We hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: Oct. 4, 2006 Signed: Alex C. Toy
Alex C. Toy

Date: Oct 4, 2006 Signed: John W. Forsberg
John W. Forsberg

EXHIBIT A



PART NO.	REV	ECO NO.	STATUS
S02014-001	D	002-4062	OBSCOLET
S02014-002	B	002-4062	ACTIVE

EXHIBIT A (cont.)

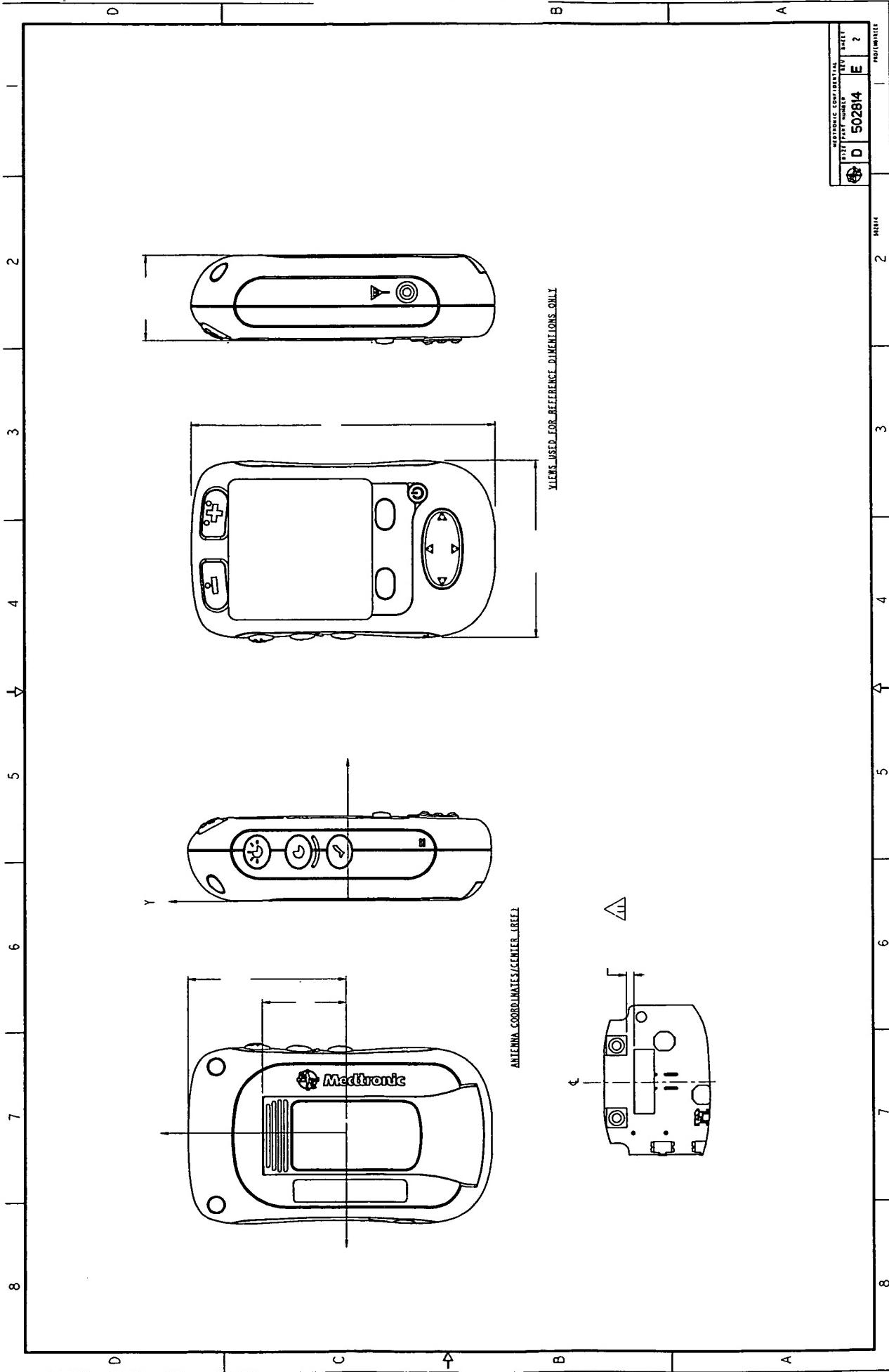


EXHIBIT B

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 1 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

Revision History:

Revision	Comments
1.0	Initial release for routing

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 2 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

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 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 3 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

1 INTRODUCTION

This document is the electrical Design Verification Test (DVT) Report for the 37741 Patient Programmer Platform.

1.1 Purpose

The purpose of this report is to document the results of test plan

1.2 Scope

This report applies only to design verification testing of the 37741 Patient Programmer Platform.

1.3 Document Overview

This document is organized as follows:

- Section 2 contains references and definitions.
- Section 3 contains a table with the list of tests, software revisions, sample sizes, and test results.
- Section 4 contains the results of the electrical design verification tests.

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 4 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

2 REFERENCES AND DEFINITIONS

This section identifies internal and external reference documents that augment the information provided in this document. It also defines terms, acronyms, and abbreviations used within the document.

2.1 Internal Medtronic References

Number	Name
120275	
215387	
288117-70040	
288117-70044	
288117-70029	
503011001	
288117-70200	

Note: Document revisions referenced in DVT Plan.

2.2 External References

Reference the PEM Electrical Specification for external specification standards.

2.3 Definitions, Acronyms, and Abbreviations

ARB: Arbitrary Waveform Generator

ARB equipment: One or more arbitrary waveform generators, used alone or in conjunction to generate sophisticated waveforms.

DUT: Device Under Test

DVT: Design Verification Test

DVT Console: The test console needed to perform the tests specified herein.

ES: Electrical Specification #120275

GPIB: General Purpose Interface Bus

PEM: Patient Electronic Module

PP: Patient Programmer

POR: Power On Reset

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 5 of 49
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3 Test Results Summary

Table 1 summarizes the results of all electrical design verification testing. Section 4 details each test setup, criteria, and results.

- Test data is stored as 288117-70200.
- Table 1 indicates test name, sample size, DUT software revision, Test Script Software revision, test path, and results.
- Test paths are shown in section 3.1.

Table 1

Test Name	Sample Size	DUT Software Revision	Script Software Test Revision	Test Path	Results
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	1				PASS

EXHIBIT B (cont.)

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Title: Neuro Patient Programmer Platform Electrical DVT Report				

3.1 Test Paths

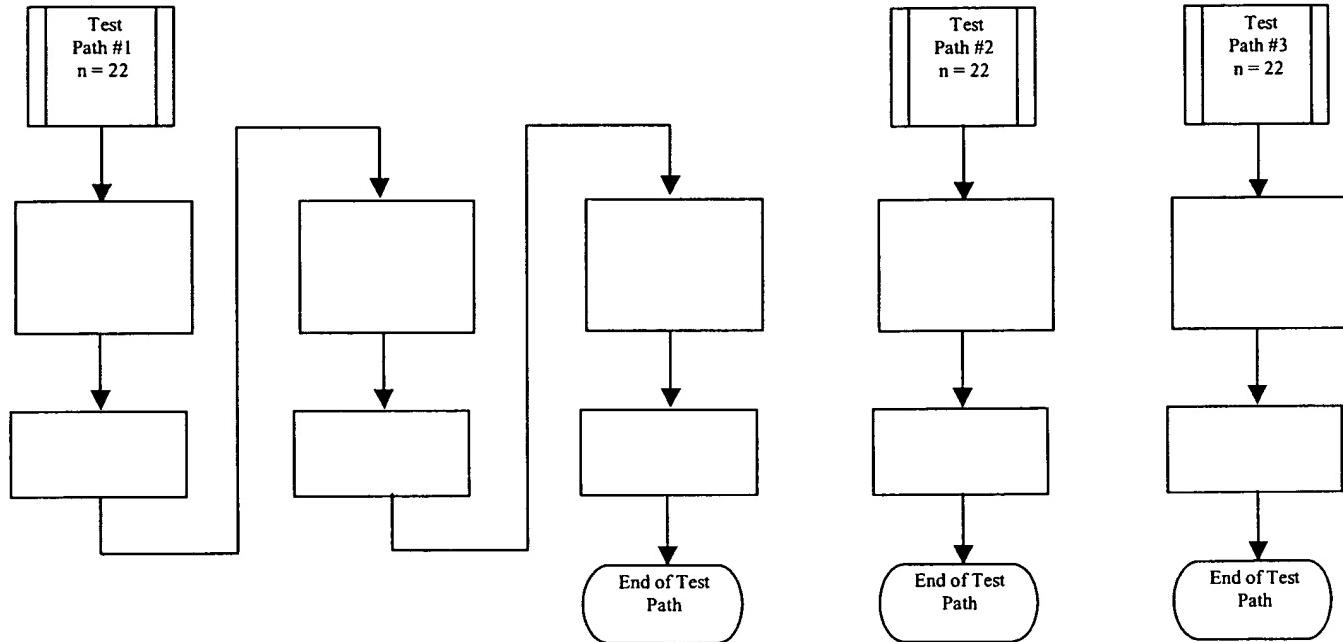


EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 7 of 49
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4 ELECTRICAL TESTS

This section specifies electrical tests performed on the 37741 Patient Programmer Platform.

4.1 Power Source Tests

4.1.1 Current Drain Test

4.1.1.1 Objective

To verify the current drain meets the requirements specified in the Power Source section of the PEM Electrical Specification.

4.1.1.2 Method and Equipment

4.1.1.3 Test Cases

There are _ test cases for transmit using all combinations of test values below:

Parameter	Test Values	Units

The

There are _ test cases using all combinations of test values below:

Parameter	Test Values	Units

There are _ test cases using two combinations of test values below:

Parameter	Test Values	Units

There are _ total test cases.

4.1.1.4 Acceptance Criteria

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 8 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

Operating Condition (Ref.)	Antenna	Duty Cycle (%)	Current Drain (mA) MAX		
			V	V	V
Row A	INT				
Row B	INT				
Row C	INT				
Row D	INT				
Row E	INT				
Row F	INT				
Row G	INT				
Row H	EXT				
Row I	INT				
Row J	INT				

Note 1:

4.1.1.5 Test Setup

- 1.
- 2.
- 3.
- 4.

4.1.1.6 Test Procedure

- 1.
- 2.

- 3.
- 4.

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 9 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

4.1.1.7 RESULTS PASS

All devices met the acceptance criteria.

Operating Condition	Current Drain (mA) MAX															
	Row	Spec	Min	Max	Mean	Std Dev	Spec	Min	Max	Mean	Std Dev	Spec	Min	Max	Mean	Std Dev
A																
B																
C																
D																
E																
F																
G																
H																
I																
J																

4.1.2 Supply Voltage Range Test

4.1.2.1 Objective

To verify the supply voltage range meets the requirements specified in the Power Source section of the PEM Electrical Specification.

4.1.2.2 Method and Equipment

4.1.2.3 Test Cases

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 10 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

Parameter	Test Values	Units

The

There is test case without transmit:

Parameter	Test Values	Units

4.1.2.4 Acceptance Criteria

Operating Condition	Antenna	H-Bridge Drive Duty Cycle (%)	Min operating voltage (V)

4.1.2.5 Test Setup

- 1.
- 2.
- 3.
- 4.

4.1.2.6 Test Procedure

- 1.
- 2.
- 3.

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 11 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

4.1.2.7 RESULTS PASS

All devices met the acceptance criteria.

Operating Condition	Antenna	Supply Voltage Range (Volts)			
		Min	Max	Avg	Std Dev

4.2 Input/Output Connections Tests**4.2.1 Keypad Interface Test****4.2.1.1 Objective**

To verify the keypad interface meets the requirements specified in the *Input/Output Connections* section of the PEM Electrical Specification.

4.2.1.2 Method and Equipment**4.2.1.3 Test Cases**

Parameter	Test Values	Units

4.2.1.4 Acceptance Criteria**4.2.1.5 Test Setup**

- 1.
- 2.
- 3.

4.2.1.6 Test Procedure

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 12 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

3.

4.2.1.7 RESULTS PASS

All devices met the acceptance criteria.

Tests	Keypad Interface (pass/fail)		
	Pass	Pass	Pass
	Pass	Pass	Pass

4.2.2 Display Interface Test**4.2.2.1 Objective**To verify the display interface meets the requirements specified in the *Input/Output Connections* section of the PEM Electrical Specification.**4.2.2.2 Method and Equipment****4.2.2.3 Test Cases**

There are test cases using combinations of the test values below:

Parameter	Test Values	Units

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 13 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

4.2.2.4 Acceptance Criteria

Test Parameters				Requirements			

4.2.2.5 Test Setup

- 1.
- 2.
- 3.

4.2.2.6 Test Procedure

- 1.
- 2.
- 3.
- 4.

4.2.2.7 RESULTS PASS

All devices met the acceptance criteria.

Test	Display Interface (pass/fail)		
	Pass	Pass	Pass
	Pass	Pass	Pass
	Pass	Pass	Pass

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 14 of 49
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4.2.3 External Antenna Interface Test

4.2.3.1 Objective

To verify the external antenna interface meets the requirements specified in the *Input/Output Connections* section of the PEM Electrical Specification.

4.2.3.2 Method and Equipment

4.2.3.3 Test Cases

There are test cases using all combinations of test values below:

Parameter	Test Values	Units

4.2.3.4 Acceptance Criteria

- When an external antenna is connected, there should be no downlink from the internal antenna.
- When an external antenna is connected, the uP should detect that the antenna is connected.

External Antenna					Yes/No
	Min	Max	Min	Max	

4.2.3.5 Test Setup

- 1.
- 2.
- 3.
- 4.
- 5.

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 15 of 49
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4.2.3.6 Test Procedure

- 1.
- 2.
- 3.
- 4.

4.2.3.7 RESULTS PASS

All devices met the acceptance criteria.

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 16 of 49
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Test Configuration		Test
		A
		B

Test	External Antenna Interface (A/m)												
	Min	Max	Mean	Std dev		Min	Max	Mean	Std dev		Min	Max	Mean
A													
B													

4.2.4 Infrared Port Interface Test

4.2.4.1 Objective

To verify the infrared port interface meets the requirements specified in the *Input/Output Connections* section of the PEM Electrical Specification. [PTPROG_PEMT-0006:1]

4.2.4.2 Method and Equipment

4.2.4.3 Test Cases

There are test cases using all combinations of test values below:

Parameter	Test Values		Units

4.2.4.4 Acceptance Criteria

All	All	None

4.2.4.5 Test Setup

- 1.
- 2.

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 17 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

3.

4.2.4.6 Test Procedure

- 1.
- 2.
- 3.
- 4.

4.2.4.7 RESULTS PASS

All devices met the acceptance criteria.

Voltage (V)	Infrared (pass/fail)								
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

4.2.5 Audio Transducer Test

4.2.5.1 Objective

To verify the audio transducer meets the requirements specified in the *Input/Output Connections* section of the PEM Electrical Specification.

4.2.5.2 Method and Equipment

4.2.5.3 Test Cases

There are test cases using all combinations of test values below:

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 18 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

Parameter	Test Values		Units

4.2.5.4 Acceptance Criteria

4.2.5.5 Test Setup

- 1.
- 2.
- 3.
- 4.
- 5.

4.2.5.6 Test Procedure

- 1.
- 2.
- 3.
- 4.

4.2.5.7 RESULTS PASS

All devices met the acceptance criteria.

	Audio Transducer (dB SPL)											
	Min	Max	Mean	Std dev	Min	Max	Mean	Std dev	Min	Max	Mean	Std dev

4.2.6 Manufacturing/Test Interface Test

Manufacturing requirements defined in Test Specification, Patient Programmer, 215387.

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 19 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

4.3 Internal Resources Tests

4.3.1 Memory Test

4.3.1.1 Objective

To verify the internal memory resources meet the requirements specified in the *Internal Resources* section of the PEM Electrical Specification.

4.3.1.2 Method and Equipment

4.3.1.3 Test Cases

There are test cases using all combinations of test values below:

Parameter	Test Values	Units

4.3.1.4 Acceptance Criteria

All	Pass

4.3.1.5 Test Setup

- 1.
- 2.
- 3.

4.3.1.6 Test Procedure

- 1.
- 2.
- 3.
- 4.

4.3.1.7 RESULTS PASS

All devices met the acceptance criteria.

Test	Memory (pass/fail)		
	Pass	Pass	Pass
	Pass	Pass	Pass
	Pass	Pass	Pass

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 20 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

4.3.2 Real-Time Clock Backup Test

4.3.2.1 Objective

To verify the real-time clock backup meets the requirements specified in the *Internal Resources* section of the PEM Electrical Specification.

4.3.2.2 Method and Equipment

4.3.2.3 Test Cases

There is one test case below:

Parameter	Test Value	Units

4.3.2.4 Acceptance Criteria

Test Case	Min Time w/o power (min)

4.3.2.5 Test Setup

- 1.
- 2.
- 3.

4.3.2.6 Test Procedure

- 1.
- 2.
- 3.
- 4.
- 5.

4.3.2.7 RESULTS PASS

All devices met the acceptance criteria.

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 21 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

Test	Real-Time Backup (pass/fail)		
	Pass	Pass	Pass

4.3.3 Real-Time Clock Accuracy Test

4.3.3.1 Objective

To verify the real-time clock accuracy meets the requirements specified in the *Internal Resources* section of the PEM Electrical Specification.

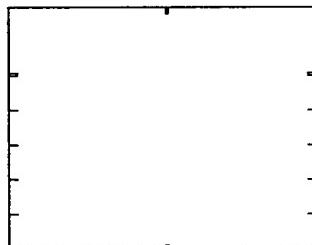
4.3.3.2 Method and Equipment

4.3.3.3 Test Cases

There are test cases (actually measurement points) using all combinations of test values below:

Parameter	Test Value	Units

4.3.3.4 Acceptance Criteria



4.3.3.5 Test Setup

- 1.
- 2.

4.3.3.6 Test Procedure

- 1.
- 2.

4.3.3.7 RESULTS PASS

All devices met the acceptance criteria.

EXHIBIT B (cont.)



Medtronic

Neurological

Document Number

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1.0

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Title: Neuro Patient Programmer Platform Electrical DVT Report

4.3.4 A/D Measurements Test

4.3.4.1 Objective

To verify the A/D measurement accuracy meets the requirements specified in the *Internal Resources* section of the PEM Electrical Specification.

4.3.4.2 Method and Equipment

4.3.4.3 Test Cases

There are test cases using the test values below:

Parameter	Test Values	Units

4.3.4.4 Acceptance Criteria

A/D Voltage	Test Value	Max Error (%)
—	—	—

4.3.4.5 Test Setup

- 1.
 - 2.
 - 3.
 - 4.

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 23 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

5.

4.3.4.6 Test Procedure

- 1.
- 2.
- 3.
- 4.

4.3.4.7 RESULTS PASS

All devices met the acceptance criteria.

EXHIBIT B (cont.)



Medtronic

Neurological

Document Number
288117-70205

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1.0

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Title: Neuro Patient Programmer Platform Electrical DVT Report

4.3.5 D/A Control Voltages Test

4.3.5.1 Objective

To verify the D/A accuracy meets the requirements specified in the *Internal Resources* section of the PEM Electrical Specification.

4.3.5.2 Method and Equipment

4.3.5.3 Test Cases

There are test cases using all combinations of test values below:

EXHIBIT B (cont.)

 Medtronic	Neurological	Document Number 288117-70205	Rev/Version 1.0	Sht 25 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

Parameter	Test Value	Units

4.3.5.4 Acceptance Criteria

D/A Voltage	Measurement point	Max % Error

4.3.5.5 Test Setup

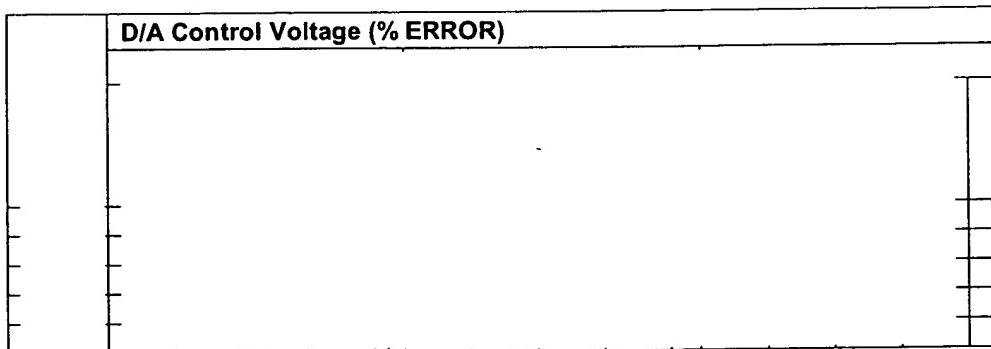
- 1.
- 2.
- 3.
- 4.

4.3.5.6 Test Procedure

- 1.
- 2.
- 3.

4.3.5.7 RESULTS PASS

All devices met the acceptance criteria.

**4.4 Transmit Telemetry (Downlink) Tests****4.4.1 Magnetic Field Intensity Test****4.4.1.1 Objective**

To verify downlink magnetic field intensity meets the requirements specified in the *Transmit Telemetry (Downlink)* section of the PEM Electrical Specification.

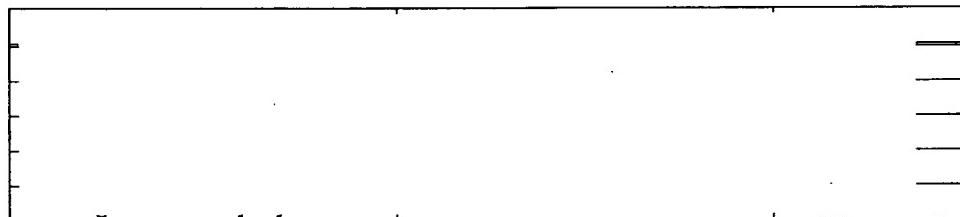
EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 26 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

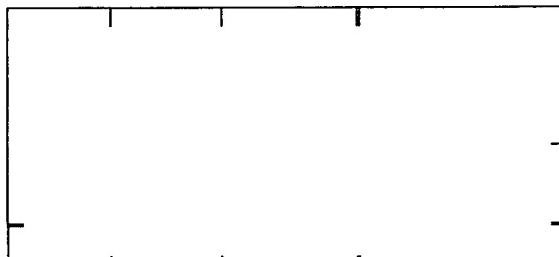
4.4.1.2 Method and Equipment

4.4.1.3 Test Cases

There are test cases at kHz using all combinations of test values below:



4.4.1.4 Acceptance Criteria



4.4.1.5 Test Setup

- 1.
- 2.
- 3.
- 4.

- 5.

4.4.1.6 Test Procedure

- 1.
- 2.

- 3.
- 4.

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 27 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

5.

4.4.1.7 RESULTS PASS

All devices met the acceptance criteria.

Magnetic Field Intensity (A/m)	

4.4.2 Burst Characteristics Test**4.4.2.1 Objective**

To verify downlink burst characteristics of width, rise time, fall time, frequency, and overshoot meet the requirements specified in the *Transmit Telemetry (Downlink)* section of the PEM Electrical Specification.

4.4.2.2 Method and Equipment**4.4.2.3 Test Cases**

There are test cases using all combinations of test values below:

Parameter	Test Values	Units

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 28 of 49
----------------------------------------------------------------------------------------------------	---------------------	---------------------------------	--------------------	-----------------

Title: Neuro Patient Programmer Platform Electrical DVT Report

4.4.2.4 Acceptance Criteria

—

4.4.2.5 Test Setup

1. 2. 3. 4. 5.

4.4.2.6 Test Procedure

1.
2.

- 3.
- 4.
- 5.

4.4.2.7 RESULTS PASS

All devices met the acceptance criteria.

EXHIBIT B (cont.)



Medtronic

Neurological

Document Number

Rev/Version
1.0

Sht
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Title: Neuro Patient Programmer Platform Electrical DVT Report

Parameter	Test	Burst Characteristics						Performance Metrics					
		Ambient Temp				Low Temp				High Temp			
		Min	Max	Mean	Std dev	Min	Max	Mean	Std dev	Min	Max	Mean	Std dev
Antenna		10.0	12.0	11.0	0.5	10.0	12.0	11.0	0.5	10.0	12.0	11.0	0.5
Voltage		10.0	12.0	11.0	0.5	10.0	12.0	11.0	0.5	10.0	12.0	11.0	0.5
Power		10.0	12.0	11.0	0.5	10.0	12.0	11.0	0.5	10.0	12.0	11.0	0.5
Frequency		10.0	12.0	11.0	0.5	10.0	12.0	11.0	0.5	10.0	12.0	11.0	0.5
Amplitude		10.0	12.0	11.0	0.5	10.0	12.0	11.0	0.5	10.0	12.0	11.0	0.5
Phase		10.0	12.0	11.0	0.5	10.0	12.0	11.0	0.5	10.0	12.0	11.0	0.5
Latency		10.0	12.0	11.0	0.5	10.0	12.0	11.0	0.5	10.0	12.0	11.0	0.5
Throughput		10.0	12.0	11.0	0.5	10.0	12.0	11.0	0.5	10.0	12.0	11.0	0.5
Error Rate		10.0	12.0	11.0	0.5	10.0	12.0	11.0	0.5	10.0	12.0	11.0	0.5
Bandwidth		10.0	12.0	11.0	0.5	10.0	12.0	11.0	0.5	10.0	12.0	11.0	0.5
Latency		10.0	12.0	11.0	0.5	10.0	12.0	11.0	0.5	10.0	12.0	11.0	0.5
Throughput		10.0	12.0	11.0	0.5	10.0	12.0	11.0	0.5	10.0	12.0	11.0	0.5
Error Rate		10.0	12.0	11.0	0.5	10.0	12.0	11.0	0.5	10.0	12.0	11.0	0.5
Bandwidth		10.0	12.0	11.0	0.5	10.0	12.0	11.0	0.5	10.0	12.0	11.0	0.5

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 30 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

4.5 Receive Telemetry (Uplink) Tests

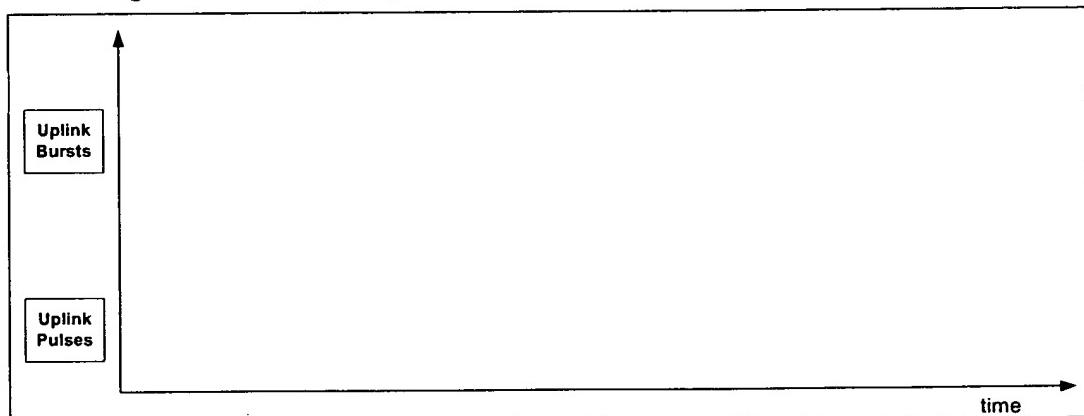
4.5.1 Detection Threshold Test

4.5.1.1 Objective

To verify uplink detection threshold (i.e. receiver sensitivity) meets the requirements specified in the *Receive Telemetry (Uplink)* section of the PEM Electrical Specification.

4.5.1.2 Method and Equipment

Figure 1: Example Uplink Detection Threshold Test Waveforms



4.5.1.3 Test Cases

There are test cases using all combinations of test values below:

Parameter	Test Values	Units

The supply voltage is 2.5 V.

EXHIBIT B (cont.)



Medtronic

Neurological

Document Number

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1.0

Sht
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Title: Neuro Patient Programmer Platform Electrical DVT Report

4.5.1.4 Acceptance Criteria

Antenna	Telemetry Type	Detection Onset (Uplink dB)	Detection Threshold (Uplink dB)	Maximum Input Level (Uplink dB)
		Max	Max	Max

4.5.1.5 Test Setup

1. 2. 3. 4. 5.

4.5.1.6 Test Procedure

1.
2.
3.
4.

4.5.1.7 RESULTS PASS

All devices met the acceptance criteria.

Antenna	Telemetry	Detection Threshold (dB)						Link Quality (dB)					
		Min	Max	Mean	Std dev	Min	Max	Mean	Std dev	Min	Max	Mean	Std dev
Antenna A	Telemetry 1	-10	-5	-7.5	1.5	-12	-7	-9.5	2.0	-15	-10	-12.5	1.0
Antenna B	Telemetry 2	-15	-10	-12.5	2.0	-18	-13	-15.5	2.5	-20	-15	-17.5	1.5
Antenna C	Telemetry 3	-20	-15	-17.5	1.5	-22	-17	-19.5	3.0	-25	-20	-22.5	2.0

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 32 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

Antenna	Telemetry	Maximum Input Level (pass/fail)		
		Pass	Pass	Pass
		Pass	Pass	Pass
		Pass	Pass	Pass
		Pass	Pass	Pass
		Pass	Pass	Pass
		Pass	Pass	Pass
		Pass	Pass	Pass

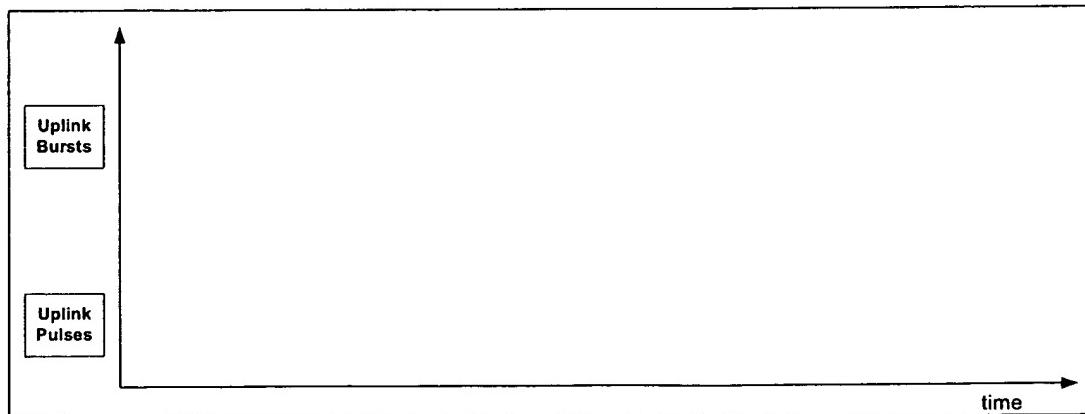
4.5.2 Detection Margin Test

4.5.2.1 Objective

To verify uplink detection margin meets the requirements specified in the *Receive Telemetry (Uplink)* section of the PEM Electrical Specification.

4.5.2.2 Method and Equipment

Figure 2: Example Uplink Detection Margin Test Waveforms



4.5.2.3 Test Cases

There are test cases using all combinations of test values below:

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 33 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

Parameter	Test Values	Units

4.5.2.4 Acceptance Criteria

Telemetry Type	Data Bursts	Amplitude A1	Antenna	Detection Margin (Uplink dB)	
				Min	Max

4.5.2.5 Test Setup

- 1.
- 2.
- 3.
- 4.

- 5.

4.5.2.6 Test Procedure

- 1.
- 2.
- 3.

- 4.

4.5.2.7 RESULTS PASS

All devices met the acceptance criteria.

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 34 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

Antenna	Telemetry	Detection Margin (dB)											
		Min	Max	Mean	Std dev	Min	Max	Mean	Std dev	Min	Max	Mean	Std dev

4.5.3 Noise Immunity Test

4.5.3.1 Objective

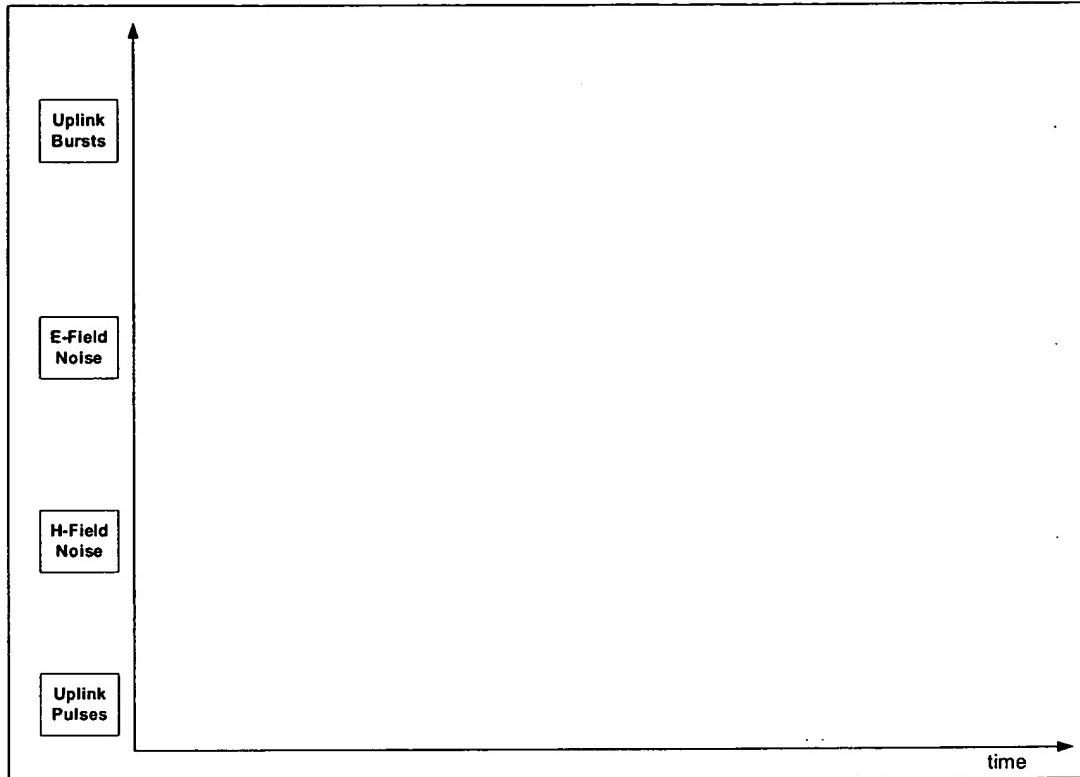
To verify uplink noise immunity meets the requirements specified in the *Receive Telemetry (Uplink)* section of the PEM Electrical Specification.

4.5.3.2 Method and Equipment

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 35 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

Figure 3: Example Uplink Noise Immunity Test Waveforms



4.5.3.3 Test Cases

There are _____ test cases using all combinations of test values below:

Parameter	Test Values	Units

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 36 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

4.5.3.4 Acceptance Criteria

Telemetry Type	Uplink Level A1 (dB)	Antenna	Min E-Noise Immunity (dB)	Min H-Noise Immunity (dB)

4.5.3.5 Test Setup

- 1.
- 2.
- 3.
- 4.
- 5.

- 6.

4.5.3.6 Test Procedure

- 1.
- 2.
- 3.
- 4.

- 5.

4.5.3.7 RESULTS PASS

All devices met the acceptance criteria.

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 37 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

Antenna	Noise	Telemetry	Noise Immunity (dB)							
			Min	Max	Mean	Std dev	Min	Max	Mean	Std dev
Antenna A	Low	Telemetry 1	-10	-5	-7.5	1.5	-12	-7	-9.5	2.0
Antenna A	High	Telemetry 1	-15	-10	-12.5	2.0	-18	-13	-15.5	2.5
Antenna B	Low	Telemetry 2	-12	-7	-9.5	1.5	-14	-9	-11.5	2.0
Antenna B	High	Telemetry 2	-18	-13	-15.5	2.5	-20	-15	-17.5	3.0
Antenna C	Low	Telemetry 3	-14	-9	-11.5	1.5	-16	-11	-14.5	2.0
Antenna C	High	Telemetry 3	-20	-15	-17.5	3.0	-22	-17	-19.5	3.5

4.5.4 Signal Distortion Test

4.5.4.1 Objective

To verify uplink signal distortion meets the requirements specified in the *Receive Telemetry (Uplink)* section of the PEM Electrical Specification.

4.5.4.2 Method and Equipment

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 38 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

4.5.4.3 Test Cases

Parameter	Test Values	Units

There are test cases for Tel A, and test cases for Tel N.

4.5.4.4 Acceptance Criteria

Telemetry Type	Uplink Level A1 (dB)	Antenna	Interval Distortion (μ s)	Active/Idle Distortion (μ s)

4.5.4.5 Test Setup

- 1.
- 2.
- 3.
- 4.

- 5.

4.5.4.6 Test Procedure

- 1.
- 2.
- 3.

- 4.

4.5.4.7 RESULTS PASS

All devices met the acceptance criteria.

EXHIBIT B (cont.)



Medtronic

Neurological

Document Number

Rev/Version
1.0

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Title: Neuro Patient Programmer Platform Electrical DVT Report

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 40 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

Antenna	Test	Uplink (dB)	Signal Distortion Telemetry N, 1's (us)											
			Min	Max	Mean	Std dev	Min	Max	Mean	Std dev	Min	Max	Mean	Std dev

4.5.5 Turnaround Time Test

4.5.5.1 Objective

To verify uplink turnaround time meets the requirements specified in the *Receive Telemetry (Uplink)* section of the PEM Electrical Specification.

4.5.5.2 Method and Equipment

4.5.5.3 Test Cases

There are test cases using all combinations of test values below:

Parameter	Test Values	Units

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 41 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

4.5.5.4 Acceptance Criteria

Supply Voltage	H-Bridge Drive Duty Cycle	Turnaround Time (mS)

4.5.5.5 Test Setup

- 1.
- 2.
- 3.

4.5.5.6 Test Procedure

- 1.
- 2.
- 3.
- 4.

4.5.5.7 RESULTS PASS

All devices met the acceptance criteria.

Test	Turnaround Time (pass/fail)

4.5.6 Hold Drift Test

4.5.6.1 Objective

To verify the hold drift meets the requirements specified in the *Receive Telemetry (Uplink)* section of the PEM Electrical Specification.

4.5.6.2 Method and Equipment

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 42 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

4.5.6.3 Test Cases

There is test case:

Parameter	Uplink Level	Units

4.5.6.4 Acceptance Criteria

Time after hold circuit enabled	Max Hold Drift

4.5.6.5 Test Setup

- 1.
- 2.
- 3.

4.5.6.6 Test Procedure

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.
- 8.
- 9.
- 10.

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 43 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

4.5.6.7 RESULTS PASS

All devices met the acceptance criteria.

Hold Drift (mV)

4.5.7 New-Battery FET Test**4.5.7.1 Objective**

To verify that enabling the new-battery FET circuit reduces the receiver noise floor (ambient RF energy detected by the receiver circuit) when new batteries are used.

4.5.7.2 Method and Equipment**4.5.7.3 Test Cases**

There is test case:

Parameter	Uplink Level	Units

4.5.7.4 Acceptance Criteria

Supply Voltage	New-Battery FET	RSSI Peak

4.5.7.5 Test Setup

- 1.
- 2.
- 3.

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 44 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

4.5.7.6 Test Procedure

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.

4.5.7.7 RESULTS PASS

All devices met the acceptance criteria.

	New-Battery FET (mV)											
	Min	Max	Mean	Std dev	Min	Max	Mean	Std dev	Min	Max	Mean	Std dev

4.6 Telemetry Performance Tests

4.6.1 Telemetry Map Area at a Fixed Distance Test

4.6.1.1 Objective

To verify telemetry performance in terms of map area at a fixed distance meets the requirements specified in the *Telemetry Performance* section of the PEM Electrical Specification.

4.6.1.2 Method and Equipment

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 45 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

4.6.1.3 Test Cases

Parameter	Test Values	Units

There are test cases.

4.6.1.4 Acceptance Criteria

IPG	Antenna	Map Area @ 5cm

4.6.1.5 Test Setup

- 1.
- 2.

4.6.1.6 Test Procedure

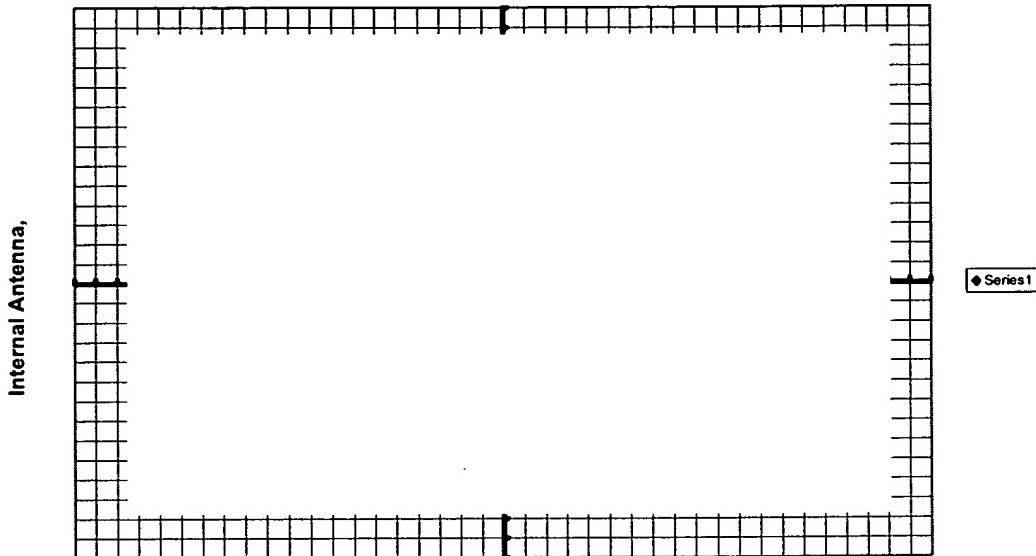
- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.
- 8.

4.6.1.7 RESULTS PASS

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 46 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

4.6.1.7.1 Internal Antenna Map @



4.6.1.7.2 Internal Antenna @

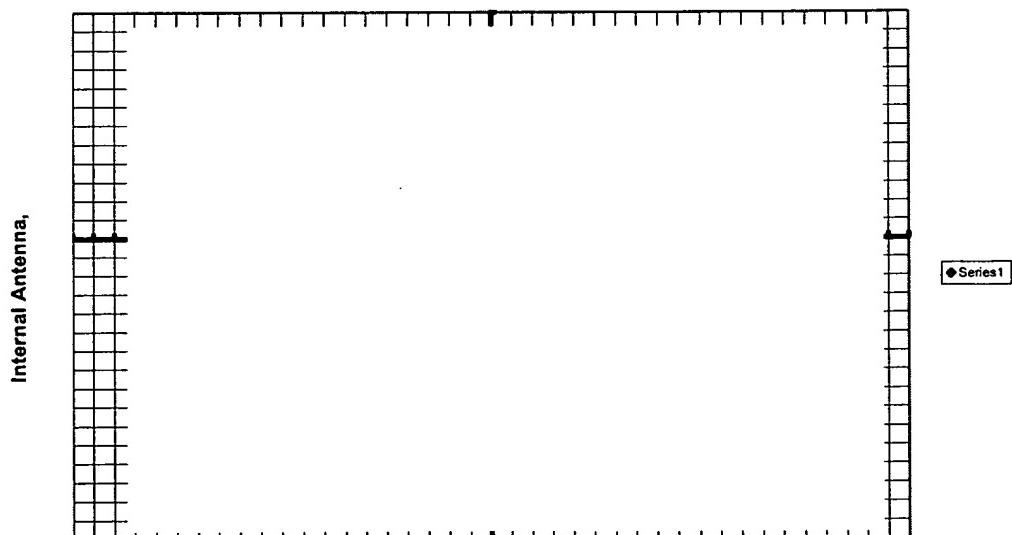
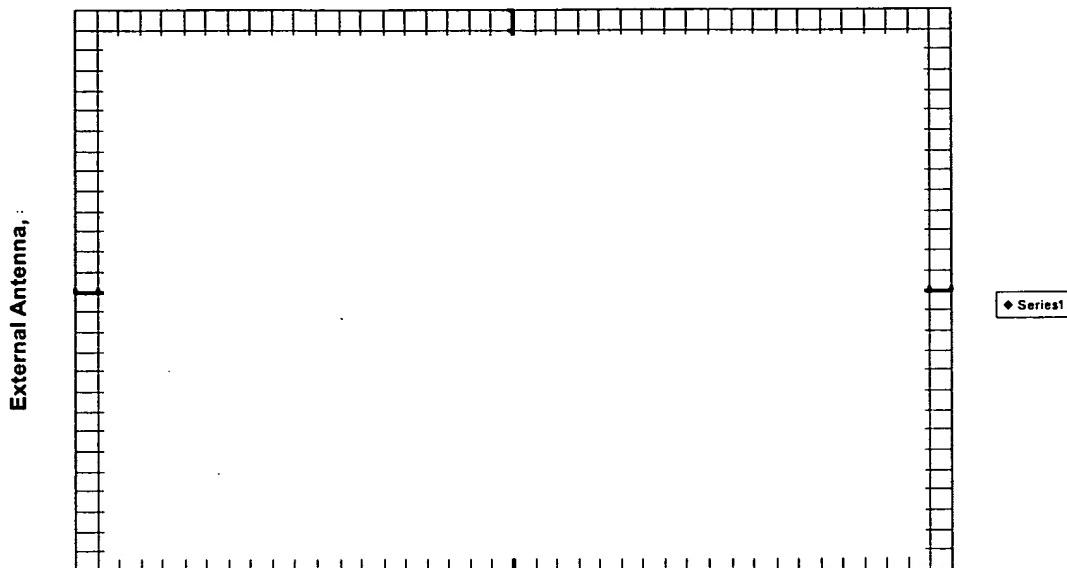


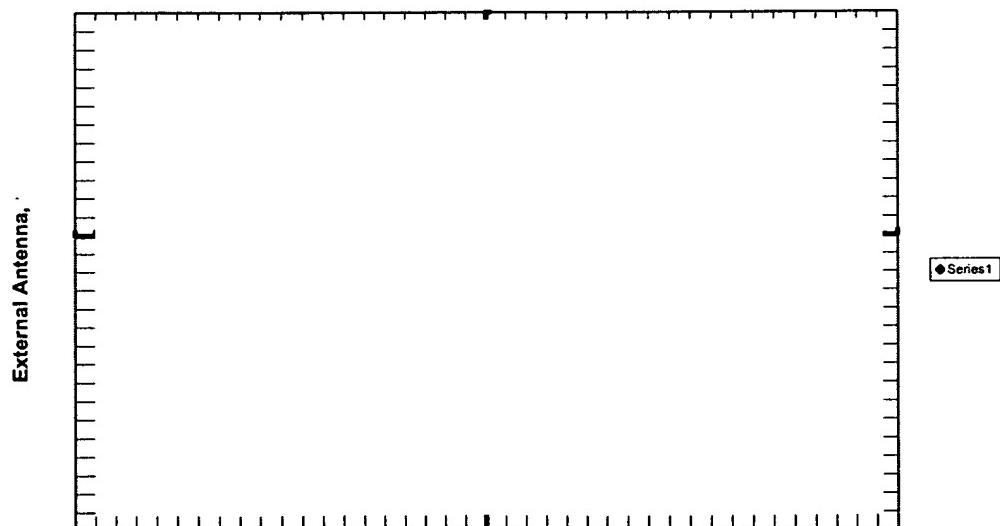
EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 47 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

4.6.1.7.3 External Antenna Map @



4.6.1.7.4 External Antenna @

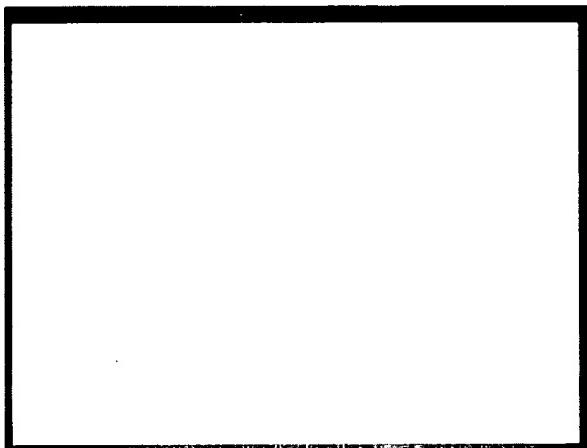


4.6.1.7.5 Photo of test fixture showing

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 48 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

in this photo.



4.6.1.7.6 Photo of

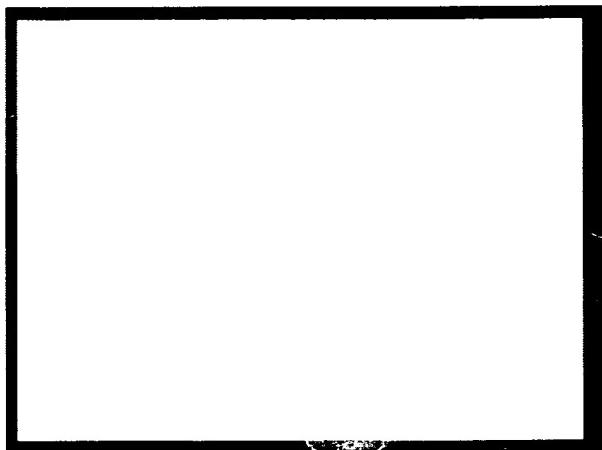


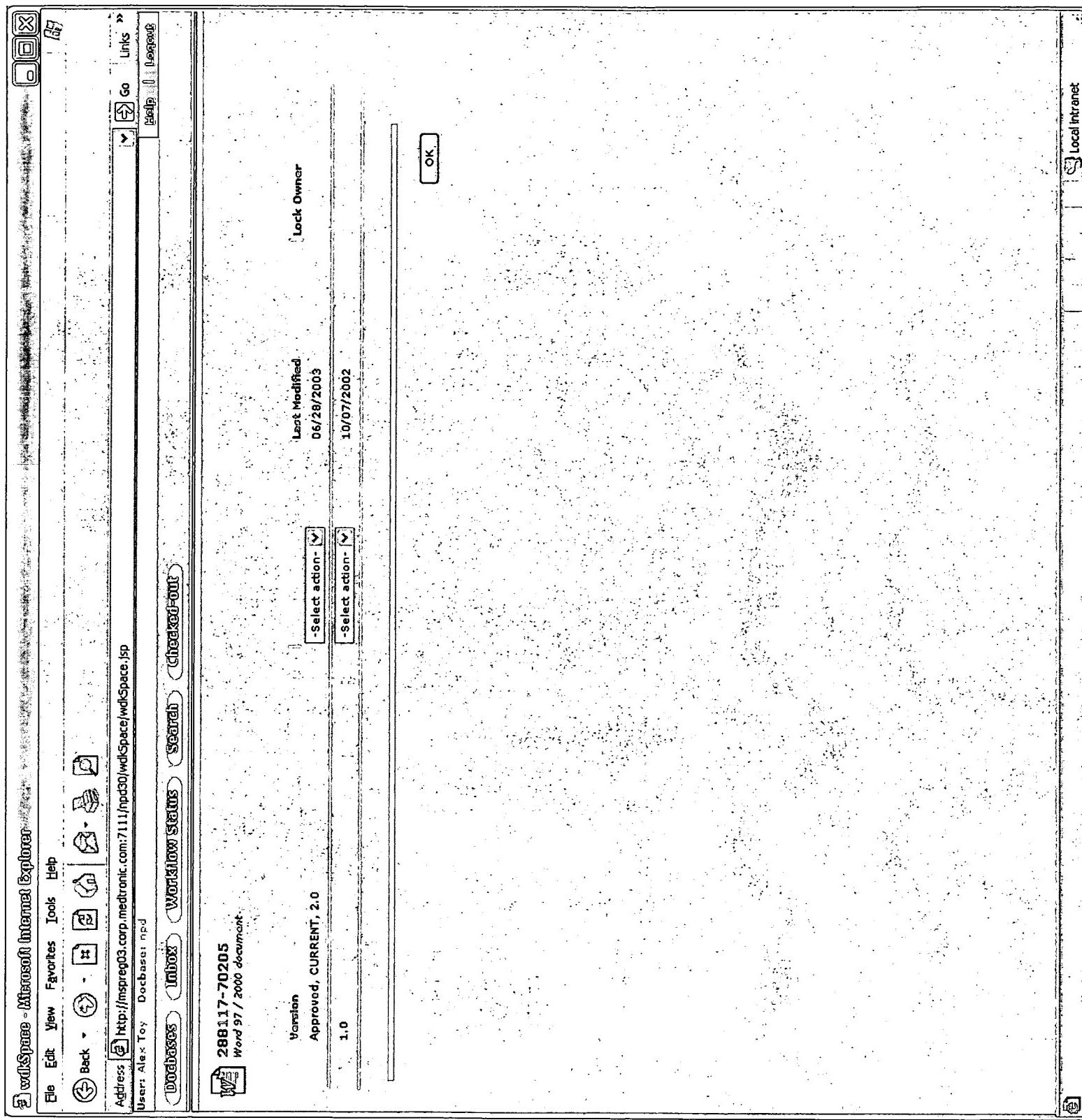
EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 49 of 49
Title: Neuro Patient Programmer Platform Electrical DVT Report				

5 COMPLETION

This paragraph concludes this test specification.

Exhibit C



Test Path #1 from DVT Plan 288117-70020 Section 7.0

DVT Pre-Test Performed to verify operational units.

Serial Number	Buttons operational	Audio	LCD	Battery contact	Battery Door	Real time clock	IR	Backlight	Communication	Results
NJD000018P	x	x	x	x	x	x	x	x	x	OK
NJD000019P	x	x	x	x	x	x	x	x	x	OK
NJD000020P	x	x	x	x	x	x	x	x	x	OK
NJD000022P	x	x	x	x	x	x	x	x	x	OK
NJD000024P	x	x	x	x	x	x	x	x	x	OK
NJD000025P	x	x	x	x	x	x	x	x	x	OK
NJD000026P	x	x	x	x	x	x	x	x	x	OK
NJD000028P	x	x	x	x	x	x	x	x	x	OK
NJD000031P	x	x	x	x	x	x	x	x	x	OK
NJD000033P	x	x	x	x	x	x	x	x	x	OK
NJD000034P	x	x	x	x	x	x	x	x	x	OK
NJD000035P	x	x	x	x	x	x	x	x	x	OK
NJD000036P	x	x	x	x	x	x	x	x	x	OK
NJD000037P	x	x	x	x	x	x	x	x	x	OK
NJD000077P	x	x	x	x	x	x	x	x	x	OK
NJD000078P	x	x	x	x	x	x	x	x	x	OK
NJD000079P	x	x	x	x	x	x	x	x	x	OK
NJD000080P	x	x	x	x	x	x	x	x	x	OK
NJD000138P	x	x	x	x	x	x	x	x	x	OK
NJD000139P	x	x	x	x	x	x	x	x	x	OK
NJD000140P	x	x	x	x	x	x	x	x	x	OK
NJD000149P	x	x	x	x	x	x	x	x	x	OK

Testing performed by _____ Date: 23-May-02

EQUIPMENT:

Exhibit D (cont.)

PAR# 5365 **TEST PLAN: 288117-70020**
 Patient Programmer for Neuro devices.
 DATE: 29 MAY 02

SUMMERY SHEET

TECH:

SERIAL#	VISUAL	INITIAL VISUAL & ELECTRICAL		Requestor
		did functional	 	
NJD000018P	O.K.	X		
NJD000019P	O.K.	X		
NJD000020P	O.K.	X		
NJD000022P	O.K.	X		
NJD000024P	O.K.	X		
NJD000025P	O.K.	X		
NJD000026P	O.K.	X		
NJD000028P	O.K.	X		
NJD000031P	O.K.	X		
NJD000033P	O.K.	X		
NJD000034P	O.K.	X		
NJD000035P	O.K.	X		
NJD000036P	O.K.	X		
NJD000037P	O.K.	X		
NJD000077P	O.K.	X		
NJD000078P	O.K.	X		
NJD000079P	O.K.	X		
NJD000080P	O.K.	X		
NJD000138P	O.K.	X		
NJD000139P	O.K.	X		
NJD000140P	O.K.	X		
NJD000149P	O.K.	X		
	3-Jun			

RESULTS: NO ANOMALIES NOTED

Exhibit D (cont.)

SUMMERY SHEET**TEST PLAN: 288117-70020**

Patient Programmer for Neuro devices.

Life

cycle of battery contacts and door, and external antenna jack.

DATE:

19-Jun-02

Subject samples

Serial Number	Battery Door	Battery External Contact Antenna	Dimension	Weight				
	number	cycles		cycles	cycles	w/o batteries	2 AA batteries	Total Weight
NJD000018P						6.3.2		
NJD000019P						oz.	oz.	oz.
NJD000020P								
NJD000022P								
NJD000024P								
NJD000025P								
NJD000026P								
NJD000028P								
NJD000031P								
NJD000033P								
NJD000034P								
NJD000035P								
NJD000036P								
NJD000037P								
NJD000077P								
NJD000078P								
NJD000079P								
NJD000080P								
NJD000138P								
NJD000139P								
NJD000140P								
NJD000149P								

Average

Test Path #1

DVT Test Data for 288117-70020

Revision 4.0

Std Dev
Dimensions per print 502814

EQUIPMENT:

Exhibit D (cont.)

288117-70183

Page 4 of 29

Exhibit D (cont.)

SUMMERY SHEET**TECH:**

PAR# 5365 **TEST PLAN: 288117-70020**
Patient Programmer for Neuro devices. **Storage Temperature paragraph 6.2.2 of test plan.**
DATE: **19-Jun-02** **All Functional Testing done per 6.1 except backlight and IR port.**
Subject samples to low temp. storage of **degrees F for** **hours then** **degrees F for** **hours.**
Functional test samples post each temperature storage.

Serial #	Functional	Functional
NJD000018P		
NJD000019P		
NJD000020P		
NJD000022P		
NJD000024P		
NJD000025P		
NJD000026P		
NJD000028P		
NJD000031P		
NJD000033P		
NJD000034P		
NJD000035P		
NJD000036P		
NJD000037P		
NJD000077P		
NJD000078P		
NJD000079P		
NJD000080P		
NJD000138P		
NJD000139P		
NJD000140P		
NJD000149P		
Date: Complete	18-Jun	18-Jun
	19-Jun	19-Jun
		19-Jun

NOTES:

A=

B=

C=

Results:

Test Path #1

DVT Test Data for 288117-70020

Revision 4.0

EQUIPMENT:

Exhibit D (cont.)

288117-70183

Page 6 of 29

PART# 5365
Patient Programmer for Neuro devices.
DATE: 4-Jun-02 **Subject samples to Low temp. storage of** **degrees F for** **hours then** **degrees F for** **hours.**

Serial #	Low temp.	Functional	High Temp.	Functional
NJD000018P				
NJD000019P				
NJD000020P				
NJD000022P				
NJD000024P				
NJD000025P				
NJD000026P				
NJD000028P				
NJD000031P				
NJD000033P				
NJD000034P				
NJD000035P				
NJD000036P				
NJD000037P				
NJD000077P				
NJD000078P				
NJD000079P				
NJD000080P				
NJD000138P				
NJD000139P				
NJD000140P				
NJD000149P				
Date: Complete	4-Jun	4-Jun	5-Jun	5-Jun

TEST PLAN: 288117-70020				
TECH:				
	Operating Temperature paragraph 6.2.1 of test plan.			
	4-Jun-02	All Functional Testing done per 6.1 except backlight and IR port.		
Subject	samples to	Low temp. storage of	degrees F for	hours then
Serial #				
	Low temp.	Functional	High Temp.	Functional
NJD000018P				
NJD000019P				
NJD000020P				
NJD000022P				
NJD000024P				
NJD000025P				
NJD000026P				
NJD000028P				
NJD000031P				
NJD000033P				
NJD000034P				
NJD000035P				
NJD000036P				
NJD000037P				
NJD000077P				
NJD000078P				
NJD000079P				
NJD000080P				
NJD000138P				
NJD000139P				
NJD000140P				
NJD000149P				
Date: Complete	4-Jun	4-Jun	5-Jun	5-Jun

NOTES:

Results:

EQUIPMENT:

SUMMERY SHEET**TECH:****PAR# 5365**

TEST PLAN: 288117-70020
 Patient Programmer for Neuro devices.

DATE:

20-Jun-02 Thermal Shock paragraph 6.2.3 of test plan.

Subject samples to

cycles of degrees F, | degrees F, then |

Dwell at each temperature for 1 hour. All Functional Testing done per 6.1 except backlight and IR port.

	Thermal	Functional	Visual
Serial #	Shock	Testing	
NJD000018P			
NJD000019P			
NJD000020P			
NJD000022P			
NJD000024P			
NJD000025P			
NJD000026P			
NJD000028P			
NJD000031P			
NJD000033P			
NJD000034P			
NJD000035P			
NJD000036P			
NJD000037P			
NJD000077P			
NJD000078P			
NJD000079P			
NJD000080P			
NJD000138P			
NJD000139P			
NJD000140P			
NJD000149P			

NOTES: A=..**RESULTS:****EQUIPMENT:**

Exhibit D (cont.)

PAR# 5365**TEST PLAN: 288117-70020**

Patient Programmer for Neuro devices.

DATE:

21-Jun-02

Chemical Resistance paragraph 6.2.7 of test plan.

Subject samples to

SUMMERY SHEET**TECH:**

	Chemical Testing	Visual
Serial #		
NJD000018P		
NJD000019P		
NJD000020P		
NJD000022P		
NJD000024P		
NJD000025P		
NJD000026P		
NJD000028P		
NJD000031P		
NJD000033P		
NJD000034P		
NJD000035P		
NJD000036P		
NJD000037P		
NJD000077P		
NJD000078P		
NJD000079P		
NJD000080P		
NJD000138P		
NJD000139P		
NJD000140P		
NJD000149P		

RESULTS:**EQUIPMENT:**

Test Path #2 from DVT Plan 288117-70020 Section 7.0**DVT Pre-Test Performed to verify operational units.**

Serial Number	Buttons operational	Audio	LCD	Battery contact	Battery Door	Real time clock	IR	Backlight	Communication	Results
NJD000109P	x	x	x	x	x	x	x	x	x	OK
NJD000110P	x	x	x	x	x	x	x	x	x	OK
NJD000111P	x	x	x	x	x	x	x	x	x	OK
NJD000113P	x	x	x	x	x	x	x	x	x	OK
NJD000114P	x	x	x	x	x	x	x	x	x	OK
NJD000116P	x	x	x	x	x	x	x	x	x	OK
NJD000119P	x	x	x	x	x	x	x	x	x	OK
NJD000120P	x	x	x	x	x	x	x	x	x	OK
NJD000121P	x	x	x	x	x	x	x	x	x	OK
NJD000122P	x	x	x	x	x	x	x	x	x	OK
NJD000123P	x	x	x	x	x	x	x	x	x	OK
NJD000124P	x	x	x	x	x	x	x	x	x	OK
NJD000126P	x	x	x	x	x	x	x	x	x	OK
NJD000127P	x	x	x	x	x	x	x	x	x	OK
NJD000128P	x	x	x	x	x	x	x	x	x	OK
NJD000129P	x	x	x	x	x	x	x	x	x	OK
NJD000130P	x	x	x	x	x	x	x	x	x	OK
NJD000131P	x	x	x	x	x	x	x	x	x	OK
NJD000133P	x	x	x	x	x	x	x	x	x	OK
NJD000134P	x	x	x	x	x	x	x	x	x	OK
NJD000136P	x	x	x	x	x	x	x	x	x	OK
NJD000137P	x	x	x	x	x	x	x	x	x	OK

Testing performed by _____ Date: 23-May-02

EQUIPMENT: I

SUMMERY SHEET**TECH:****PAR# 5365****TEST PLAN: 288117-70020**

Patient Programmer for Neuro devices.

DATE: 29 MAY 02

INITIAL

VISUAL & ELECTRICAL

SERIAL#	VISUAL	Requestor did functional
NJDD000109P	O.K.	X
NJDD000110P	O.K.	X
NJDD000111P	O.K.	X
NJDD000113P	O.K.	X
NJDD000114P	O.K.	X
NJDD000116P	O.K.	X
NJDD000119P	O.K.	X
NJDD000120P	O.K.	X
NJDD000121P	O.K.	X
NJDD000122P	O.K.	X
NJDD000123P	O.K.	X
NJDD000124P	O.K.	X
NJDD000126P	O.K.	X
NJDD000127P	O.K.	X
NJDD000128P	O.K.	X
NJDD000129P	O.K.	X
NJDD000130P	O.K.	X
NJDD000131P	O.K.	X
NJDD000133P	O.K.	X
NJDD000134P	O.K.	X
NJDD000136P	O.K.	X
NJDD000137P	O.K.	X
	29-May	

Exhibit D (cont.)**RESULTS:**

SUMMERY SHEET**TECH:**

PAR# 5365 **TEST PLAN: 288117-70020** **Patient Programmer for Neuro devices.** **Broad Band Random Vibration paragraph 6.2.4 of test plan.**

DATE: **4-Jun-02** **All Functional Testing done per 6.1 except backlight and IR port.**

Subject samples to

SERIAL#	Back down	Visual	R. side dow	Visual	Top up	Visual	Functional	Observations
NJDD000109P								
NJDD000110P								
NJDD000111P								
NJDD000113P								
NJDD000114P								
NJDD000116P								
NJDD000119P								
NJDD000120P								
NJDD000121P								
NJDD000122P								
NJDD000123P								
NJDD000124P								
NJDD000126P								
NJDD000127P								
NJDD000128P								
NJDD000129P								
NJDD000130P								
NJDD000131P								
NJDD000133P								
NJDD000134P								
NJDD000136P								
NJDD000137P								
Date Completed	7-Jun	7-Jun	7-Jun	7-Jun	7-Jun	7-Jun	13-Jun	

NOTES:	A=
	B=
	C=

RESULTS:
EQUIPMENT:
288117-70183

SUMMERY SHEET**TECH: ROY POPE**

PART# 5365 **TEST PLAN: 288117-70020** **DATE:** 20-Jun-02 **Patient Programmer for Neuro devices.** **Mechanical Shock paragraph 6.2.5 of test plan.**
Subject samples to All Functional Testing done per 6.1 except backlight and IR port.

SERIAL#	Front	Back	Top	Bottom	Left side	Right side	Testing
NJDD000109P							
NJDD000110P							
NJDD000111P							
NJDD000113P							
NJDD000114P							
NJDD000116P							
NJDD000119P							
NJDD000120P							
NJDD000121P							
NJDD000122P							
NJDD000123P							
NJDD000124P							
NJDD000126P							
NJDD000127P							
NJDD000128P							
NJDD000129P							
NJDD000130P							
NJDD000131P							
NJDD000133P							
NJDD000134P							
NJDD000136P							
NJDD000137P							

Exhibit D (cont.)

NOTES: A=
 B=

RESULTS:

EQUIPMENT:

Test Path #3 from DVT Plan 288117-70020 Section 7.0

DVT Pre-Test Performed to verify operational units.

Serial Number	Buttons operational	Audio	LCD	Battery contact	Battery Door	Real time clock	IR	Backlight	Communication	Results
NJD000081P	x		x	x	x	x	x	x	x	OK
NJD000082P	x		x	x	x	x	x	x	x	OK
NJD000083P	x		x	x	x	x	x	x	x	OK
NJD000084P	x		x	x	x	x	x	x	x	OK
NJD000086P	x		x	x	x	x	x	x	x	OK
NJD000087P	x		x	x	x	x	x	x	x	OK
NJD000089P	x		x	x	x	x	x	x	x	OK
NJD000092P	x		x	x	x	x	x	x	x	OK
NJD000093P	x		x	x	x	x	x	x	x	OK
NJD000094P	x		x	x	x	x	x	x	x	OK
NJD000096P	x		x	x	x	x	x	x	x	OK
NJD000097P	x		x	x	x	x	x	x	x	OK
NJD000098P	x		x	x	x	x	x	x	x	OK
NJD000099P	x		x	x	x	x	x	x	x	OK
NJD000100P	x		x	x	x	x	x	x	x	OK
NJD000101P	x		x	x	x	x	x	x	x	OK
NJD000102P	x		x	x	x	x	x	x	x	OK
NJD000103P	x		x	x	x	x	x	x	x	OK
NJD000104P	x		x	x	x	x	x	x	x	OK
NJD000106P	x		x	x	x	x	x	x	x	OK
NJD000107P	x		x	x	x	x	x	x	x	OK
NJD000108P	x		x	x	x	x	x	x	x	OK

Testing performed by Date: 23-May-02

EQUIPMENT: I

Exhibit D (cont.)

PAR# 5365 **TEST PLAN: 288117-70020**
 Patient Programmer for Neuro devices.
 DATE: 29 MAY 02

INITIAL VISUAL & ELECTRICAL

TECH:

SERIAL#	VISUAL	did functional	Requestor
NJDD00081P	O.K.	X	
NJDD00082P	O.K.	X	
NJDD00083P	O.K.	X	
NJDD00084P	O.K.	X	
NJDD00086P	O.K.	X	
NJDD00087P	O.K.	X	
NJDD00089P	O.K.	X	
NJDD00092P	O.K.	X	
NJDD00093P	O.K.	X	
NJDD00094P	O.K.	X	
NJDD00096P	O.K.	X	
NJDD00097P	O.K.	X	
NJDD00098P	O.K.	X	
NJDD00099P	O.K.	X	
NJDD00100P	O.K.	X	
NJDD00101P	O.K.	X	
NJDD00102P	O.K.	X	
NJDD00103P	O.K.	X	
NJDD00104P	O.K.	X	
NJDD00106P	O.K.	X	
NJDD00107P	O.K.	X	
NJDD00108P	O.K.	X	
Date: Complete	29 May		

RESULTS: NO ANOMALIES NOTED

Exhibit D (cont.)

PAR# 5365		TEST PLAN: 288117-70020		SUMMERY SHEET		TECH:
Patient Programmer for Neuro devices.		All Functional Testing done per 6.1 except backlight and IR port.		samples to degrees F and RH for days. Test samples per request		
DATE: 29-May-02						
Subject	SERIAL#					days.
	NJD000081P					
	NJD000082P					
	NJD000083P					
	NJD000084P					
	NJD000086P					
	NJD000087P					
	NJD000089P					
	NJD000092P					
	NJD000093P					
	NJD000094P					
	NJD000096P					
	NJD000097P					
	NJD000098P					
	NJD000099P					
	NJD000100P					
	NJD000101P					
	NJD000102P					
	NJD000103P					
	NJD000104P					
	NJD000105P					
	NJD000106P					
	NJD000107P					
	NJD000108P					
Date: Complete	3-Jun	3-Jun	4-Jun	4-Jun	19-Jun	19-Jun

NOTES:

A=

B=

C=

D=

E=

F=

G=

H=

RESULTS:

Test Path #3

DVT Test Data for 288117-70020

Revision 4.0

Exhibit D (cont.)

EQUIPMENT:

|=

288117-70183

Page 17 of 29

Exhibit D (cont.)

Other Data

DVT Test Data for 288117-70020

Revision 4.0

Section 6.3.6 Button Endurance - Specification for KSS321G, used for
..... buttons (.....
Life Cycle data show life expectancy of



Exhibit D (cont.)

Other Data

DVT Test Data for 288117-70020

Revision 4.0

Section 6.3.8 Flammability - Both top and bottom housings are made from

Exhibit D (cont.)

Other Data

DVT Test Data for 288117-70020

Revision 4.0

Exhibit D (cont.)

Other Data

DVT Test Data for 288117-70020

Revision 4.0

Section 6.3.6 - Button Endurance - Specification for KSC621- Used for
top buttons /
Life Cycle data show life expectancy

Exhibit D (cont.)

Other Data

DVT Test Data for 288117-70020

Revision 4.0

4-31

Exhibit D (cont.)

Other Data

DVT Test Data for 288117-70020

Revision 4.0

Exhibit D (cont.)

Other Data

DVT Test Data for 288117-70020

Revision 4.0

Section 6.3.6 - Button Endurance - Specification for F
Used for
Life Cycle data show
life expectancy of

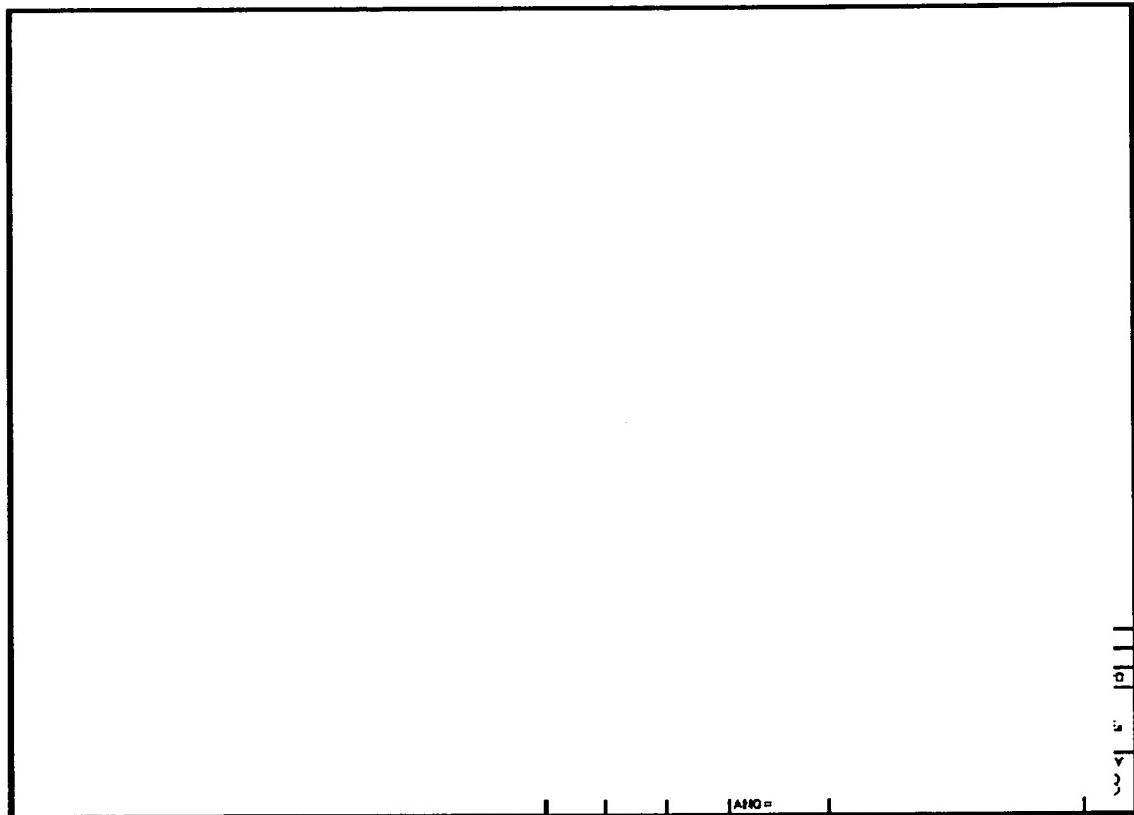


Exhibit D (cont.)

Other Data

DVT Test Data for 288117-70020

Revision 4.0

Blank Page

Exhibit D (cont.)

Other Data

DVT Test Data for 288117-70020

Revision 4.0

Exhibit D (cont.)

Other Data

DVT Test Data for 288117-70020

Revision 4.0

Section 6.3.7 Scratch resistance -



Exhibit D (cont.)

Other Data

DVT Test Data for 288117-70020

Revision 4.0

Exhibit D (cont.)

Other Data

DVT Test Data for 288117-70020

Revision 4.0

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